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10/580,873	03/01/2007	Javier Ara Pinilla	0064-PO4079US00	7301
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DANN, DORFMAN, HERRELL & SKILLMAN			EXAMINER	
1601 MARKET STREET			DUFOUR, DEVANIE A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,873	Applicant(s) ARA PINILLA ET AL.
	Examiner DEVANIE DUFOUR	Art Unit 3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-4 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 25 May 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Claim Objections

Claim 1 is objected to because of the following informalities: Line two recites "consists of". The term "consisting of" defines the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim (MPEP 2111.03). Dependent claim 2 and 3 disclose additional components- a support, a radial fin, a collar- which is excluded from the nail as defined by claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 4 describes "said probe including a head, a plurality of thin rods of considerable length extending from said head and having an intermediate node". The specifications describe the nail, not the probe, includes the plurality of thin rods which converge toward a node. The probe includes the protrusion that spread apart the rods. The apparatus of claim 4 appears to be non-functional since the probe contains the thin rods.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 recites the limitation "the functional combination" in lines 2-3, "the node" in line 6, "the terminal section" in line 9, "the proximal area" in line 11. There is insufficient antecedent basis for these limitations in the claim. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, line 4 recites "which includes a head". It is unclear if the tubular nail or the probe contains the head. The use of the term "they" in line 6 and the term "its" in line 11 is also unclear.

Claim 3 recites the limitation "the holes of the support" in line 4 and "the threaded rod" in line 5. There is insufficient antecedent basis for these limitations in the claim. Claim 3, line 4 recites "which is situated in line with the holes". It is unclear what component is in line with the holes.

In claim 3 there exists an inconsistency between the language of the body of the claim, thus making the scope of the claim unclear. In line 3, applicant recites "a threaded section" with the template being only functionally recited, i.e. "for the attachment of a template", thus indicating that the claim is directed to the subcombination, "a threaded section". However, in line 4, applicant positively recites (as best understood) the template as part of the invention, i.e. "which is situated in line with the holes", thus indicating that the combination, a threaded section and a template, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claim is intended to be directed, and amend the claim such that the

language thereof is consistent with this intent. For examination purposes claim 3 will be considered as being drawn to the subcombination, a threaded section.

Claim 4 recites the limitation "the functional combination" in lines 2-3, "the terminal section" in line 9, and "the proximal area" in line 11. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 as best understood are rejected under 35 U.S.C. 102(b) as being anticipated by Summerlin et al. (U.S. Pat. No. 3,512,448).

Summerlin et al. discloses an intramedullary nail, which is specially designed to secure and immobilize fractures in long bones such as the femur, characterized in that it consists of the functional combination of a tubular nail (Fig. 2, 11) and a probe (12) that can move axially inside the nail, which includes a head (head of nail, 28) from which a plurality of thin rods (21) of a considerable length extend, which are grouped according to an imaginary cylindrical surface and converge towards the node (18), beyond which they extend in considerably wide sections (17) that are independent at their free ends (17, as shown), whilst the probe (12) includes a protrusion (14) close to its distal end, which is initially situated outside the nail and first causes the radial deformation of the terminal section of the rods (17) during the axial movement of the probe

relative to the nail and then causes the node (18) to move towards the head (28), which in turn causes a radial expansion of the nail in the proximal area of its rods (21).

Intramedullary nail characterized in that a support (Fig. 2, 13 and 29) works with the head (28) of the nail, being the only element of the assembly that is fixed by screws to the bone, specifically at the proximal end thereof (as shown 13 and 29 are located at proximal end of nail), this support (13 and 29) having a stepped axial hole (hole in nut 13 to hole of washer 29 is a stepped axial hole) for attachment of the head (29) and a radial fin (37) with a hole (hole 36) for screwing the support to the bone.

Intramedullary nail characterized in that inside the axial hole (hole of 13 and 29) in the support, specifically at the outer end thereof (hole of 13), there is a threaded section (internal threaded hole of 13) for the attachment of a template for drilling into the bone, which is situated in line with the holes of the support and for the subsequent implantation of a collar that can move the threaded rod that constitutes the probe in order to displace the protrusion thereon towards the head of the nail (the device of Summerlin et al. is capable of utilizing the threaded section for the attachment of a template for drilling into the bone, which is situated in line with the holes of the support and for the subsequent implantation of a collar that can move the threaded rod that constitutes the probe in order to displace the protrusion thereon towards the head of the nail.

With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Summerlin et al. which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).)

Summerlin et al. discloses an intramedullary nail, which is specially designed to secure and immobilize fractures in long bones such as the femur, characterized in that it consists of the functional combination of a tubular nail (Fig. 2, 11) and a probe (12) at least coextensive in length with the nail and movable axially inside the nail, said probe including a head (28), a plurality of thin rods (21 and 17) of a considerable length extending from said head and having an intermediate node (18), said rods being grouped according to an imaginary cylindrical surface and converging towards the node independent at their free ends (17 as shown), said probe including a protrusion (14) close to its distal end, which is adapted to initially extend beyond the nail and upon withdrawal to within the nail, causes the radial deformation of the terminal section of the rods (17) during the axial withdrawal of the probe through the nail and then causes the node (18) to move towards the head which in turn causes a radial expansion of the nail in the proximal area of the rods (21) between the head and said node.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-3 as best understood are rejected under 35 U.S.C. 103(a) as being unpatentable over Summerlin et al. (U.S. Pat. No. 3,512,448).

Summerlin et al. discloses the claimed invention except for a pair of holes for screwing the support to the bone. It would have been obvious to one having ordinary skill in the art at the

time the invention was made to construct the assembly of Summerlin et al. having a pair of holes instead of one disclosed hole (Fig. 2, 36), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See form 892.

Abstract for SU 662082: The fixation of tubular bone fracture is improved using a rod (4) terminating in a support head (5) while the other end carries the adjusting nut (6). The outside surface of the hollow cylinder (1) is slotted, and is inserted into the medullary channel when in collapsed state. After the insertion, the bone fragments are aligned and the fixator is moved into the distal fragment direction adjusting the protrusion to 1.5-2 cm with the aid of nut (6). Further movement of the nut expands the slotted cylinder in the medullary channel (7) to lock the fragments.

Abstract for FR 2606269: The present invention relates to a lockable centromedullary nail for osteosynthesis of long bones, comprising a tube and a sliding inner rod bearing a pair of opposite anchoring plates which are hinged to the rod. This centromedullary nail is characterised in that the means withdrawing the anchoring plates consist of a part 16, of variable length and forming a spacer, which is housed in the base of the tube 3 and against which the edges 14a, 15a of the plates 14, 15 abut axially at the end of the introduction travel of the plate holder rod 6, so that an additional thrust exerted on the plate holder rod 6 causes the plates 14, 15 to pivot outwards and leave through the slots 4, 5 in the tube.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEVANIE DUFOUR whose telephone number is (571)270-7843. The examiner can normally be reached on Mon-Thurs 7:00 a.m.-5:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733